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Preventing Cross-Contamination in Endoscope Processing: FDA Safety Communication

Safety Communication from FDA, CDC, and the VA

Issued

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This communication cautions healthcare facilities, including hospitals, ambulatory care facilities and private practices, about the risks to patients if flexible endoscopes and their accessories are not processed properly, and recommends steps to reduce these risks. It is being issued jointly by the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, and the Department of Veterans Affairs, and has been reviewed by The Joint Commission. The communication also reminds manufacturers of endoscopes and endoscope processing equipment of their responsibilities in helping assure proper endoscope processing in healthcare facilities.

The Public Health Problem

If flexible endoscopes or endoscopic accessories are not properly processed, patients can be exposed to body fluids and tissue contaminants from prior patients, which can result in the transmission of pathogens and affect large numbers of people. Recent reports to FDA of processing errors with flexible endoscopes have highlighted the continuing importance of this issue. Reported errors included the use of improper accessories for endoscopy irrigation set-ups, improper reprocessing intervals for reusable endoscopy accessories, failure to discard single use accessories, and failure to follow the manufacturer's instructions for endoscope reprocessing.

Flexible endoscopes are fundamentally difficult to clean and disinfect or sterilize. Because of this, it is essential that facilities establish a quality system program that covers all aspects of endoscopy procedure management. Adequate patient protection can only be achieved by vigorous compliance with such a program.

General Recommendations for Healthcare Facilities

- Establish an institutional program for endoscope processing, along with written procedures for monitoring adherence to the program and a chain of accountability. Ensure that those responsible for endoscope processing understand the importance of this job and that they maintain proficiency in performing it for each type of endoscope they handle.
- Train employees to set-up, clean, disinfect or sterilize, and store endoscopy equipment properly. Periodically retrain and assess competence. Endoscopy is a constantly evolving technology, so it is essential to stay up to date with the specifics of each device your institution uses.
- Instruct staff to read and follow the endoscope manufacturer's instructions for use. People responsible for reprocessing endoscopes must have the manufacturer's instructions available for each endoscope and its accessories, because various endoscopes and their accessories often must be processed differently (e.g., most flexible endoscopic equipment cannot tolerate steam sterilization).
- Be sure staff members understand that the cleaning and disinfecting of endoscopes are **two separate processes**. Thorough cleaning of the endoscope must be done first, in order to remove gross contamination and debris. Without this step, the endoscope cannot be effectively disinfected or sterilized. Cleaning should begin immediately after use by thoroughly flushing the channels and rinsing/wiping the outside of the endoscope. This must be followed by a very thorough cleaning with brushes, concentrating especially on the channels. Only then is the endoscope ready for high level disinfection, which can be done manually or in an automatic endoscope reprocessor (AER). During disinfection, the high level disinfectant must contact **every** contaminated surface/channel for the time recommended by the disinfectant manufacturer.
- Be sure that the AER or sterilizer is compatible with the endoscope. Before using an AER, confirm that it properly fits the endoscope. Adhere to the AER or sterilizer instructions that specify which endoscope makes and models it can process. And be sure that the instructions for endoscopes, AERs and germicides do not contradict one another. If you become aware that instructions are contradictory, inform the endoscope and AER manufacturers as well as FDA.
- Be sure that endoscopes or accessories that contact sterile tissue are sterilized before each use, and that endoscopes that contact intact mucous membranes (e.g., the respiratory and gastrointestinal tracts) undergo at least high-level disinfection before each use.


For more specific recommendations, see “Endoscopy Processing for Healthcare Facilities” below. Also see the reference section, which includes citations to other guidelines and documents that provide more comprehensive information.

Adverse Event Reporting for Healthcare Facilities

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect a reportable adverse event associated with endoscopes and endoscope processing, you should follow the reporting procedure established by your facility. Prompt reporting of adverse events can improve FDA's understanding of and ability to communicate the risks associated with devices, and assist in the identification of potential future problems associated with medical devices.

We also encourage you to report any medical device adverse events related to endoscopes and endoscope processing that do not meet the requirements for mandatory reporting. You can report these directly to the device manufacturer or to MedWatch, the FDA's voluntary reporting program. This can be done on-line by filing a **voluntary report**


(<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>), by phone at 1-800-FDA-1088 , or obtain the **fillable form**

(<http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>) online, print it and fax to 1-800-FDA-0178  or mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.

Responsibilities of Manufacturers

- Be sure that the instructions for processing your flexible endoscopes and accessories are easily accessible to users, that they are complete and easy to understand, and that the steps follow in logical sequence.
- Be sure that updated versions of reprocessing instructions are communicated promptly to users.
- Be sure that instructions for each AER specify which endoscope makes and models it can process. And be sure that the instructions for endoscopes, AERs and germicides do not contradict one another. If you become aware that instructions are contradictory, you should proactively notify your customers and provide necessary recommendations.
- Evaluate and recommend reprocessing products and AERs that can be used with your endoscope. Be sure your instructions for use clearly list any reprocessing products that are not compatible with your endoscope. If possible, conduct or facilitate training for personnel in healthcare facilities on the proper processing of your endoscopes or accessories.
- Use your complaint files, as well as information provided by your field staff, to monitor problems in the processing of your endoscopes and accessories. Consider this information in the design of future endoscopes.
- If possible, work with other manufacturers to help ensure that various makes and models of endoscopes, endoscope accessories and AERs are compatible. For example, AER manufacturers should be sure that their AER's channel connections fit properly on the endoscopes specified for use with their product.
- Investigate any reports of infection or pseudoinfection clusters associated with your device so you can take appropriate corrective action. Report to FDA any information or actions that are subject to reporting under current regulations.
- Remember that you must report to FDA no later than 30 calendar days after becoming aware of information that reasonably suggests that:
 - One of your devices has caused or contributed to a death or serious injury or,
 - One of your devices has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Obtaining Additional Information

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at **DSMICA@CDRH.FDA.GOV** (<mailto:DSMICA@CDRH.FDA.GOV>) or 800-638-2041 .

ENDOSCOPY PROCESSING FOR HEALTHCARE FACILITIES

FDA recommends the following procedures to reduce the risks of transmitting infections in processing endoscopes and accessories. This applies to hospitals, ambulatory care facilities and private practices.

These recommendations are intended to reinforce the importance of following well established guidelines for processing endoscopes, and the importance of establishing a quality program. They are not intended to be all inclusive or comprehensive. Refer to the **CDC/HICPAC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008** (http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf), and the Multi-society guideline for reprocessing flexible gastrointestinal endoscopes, 2003, for comprehensive information on endoscope processing and quality control.

I. Administrative Aspects

A. Establish an institutional program and procedures for monitoring adherence to the program

1. Establish a comprehensive Quality Assurance and Safety Program for all aspects of all endoscopy procedures. It is senior level management's responsibility to establish such a program and to assign responsibility for its implementation. The program should:
 - a. Identify all staff involved in endoscopy procedures, as well as all departments, if appropriate. Include supervisors and all staff involved in these activities, specifying their position descriptions and responsibilities.
 - b. Establish set-up, break-down and reprocessing (i.e., cleaning and disinfecting or sterilizing) procedures for each type of endoscopy performed by your facility.
 - c. Identify all endoscopes, endoscope accessories and endoscope reprocessing equipment used in your facility, including: manufacturer, models, serial numbers or hospital specific equipment tag numbers, and unique device identifiers (UDIs). Include location within the facility, age, and status (e.g., maintenance schedule).
 - d. Establish and document training programs for all staff responsible for the set-up, disassembly, and reprocessing of endoscopy equipment. The program should outline schedules for periodic retraining.
 - e. Develop procedures and responsibilities for tracking the useful life of endoscopes and accessory equipment, including equipment and supplies for reprocessing. These procedures should address specification evaluation, acquisition management, scheduled maintenance, and removal of equipment from use.
 - f. Using information in product labeling, assure that the endoscopes and accessories used in your facility are compatible with your reprocessing equipment and supplies. If the labeling is unclear regarding compatibility, contact the manufacturer. Ensure that new equipment is compatible with your existing products.
 - g. Review and update procedures at regular intervals
 - h. Disseminate procedures to all involved staff, post procedures in prominent locations, and ensure all staff know where full copies of the procedures are located.

2. Establish appropriate standard operating procedures (SOPs) for preparing endoscopes for patient contact. Be sure this information does not conflict with the instructions from the manufacturers of the endoscopes, AERs, and liquid chemical sterilants/high level disinfectants (LCS/HLD). Ensure that your staff adheres to these procedures.

- a. Confirm that you have the correct versions of the instructions for the endoscope models used at your facility.
- b. Confirm that you have the correct versions of the instructions for the AERs used in your facility.
- c. Provide staff with written device-specific instructions for every endoscope model and reprocessing system you use. This may include more detailed explanations than the original manufacturers' instructions. Inform manufacturers, as well as FDA, if you believe their instructions are unclear or inadequate.
- d. Review the written reprocessing instructions from the AER manufacturers to be sure that they apply to the endoscopes used in your facility, and that they are correctly implemented.

3. Implement a comprehensive quality control program for reprocessing endoscopes and their accessories. Your reprocessing program should include:

- a. Visual inspections and testing of the equipment to identify conditions that may affect the cleaning or disinfecting processes, such as testing for leaks, examination for cracks, and checking the integrity of fiber optic bundles.
- b. Assurance that all manufacturer-recommended maintenance schedules and services are performed for all endoscopes and AERs used in your facility.
- c. The use of appropriate process monitors as recommended by your AER and germicide manufacturers.
- d. Records of the use of each endoscope, including model, serial number, and unique hospital identifier or standardized unique device identifier. Records should document the patient upon whom the endoscope was used, the date and time of use, the room location of use, and the type of procedure involved. Records should also show the system (particular model and serial number of the AER if applicable) used to reprocess the endoscope and the initials of the person(s) responsible for reprocessing the scope.
- e. A method for detecting clusters of infections or pseudoinfections associated with endoscopic procedures (e.g., a surveillance system). If a cluster is discovered, this should be reported to the manufacturer of the endoscope, the endoscope accessories, the AER, and the germicide.
- f. Documentation of all training for all staff.
- g. Documentation of all repairs for all equipment.
- h. Documentation of the introduction (and withdrawal from use) of all endoscopes, endoscope accessories, AERs and AER accessories such as scope connection devices.

B. Train, retrain, and establish a chain of accountability for endoscope processing procedures

1. Provide and document comprehensive and intensive training for all staff assigned to reprocessing endoscopes to ensure that they understand how to perform their assigned duties and the importance of proper reprocessing of all endoscopes used in your facility. All staff involved in endoscope reprocessing should be identified, provided appropriate education for their duties before beginning, observed for competence, and retrained at designated intervals. Training should include:

- a. Instruction in proper procedures, equipment connections, and which items are single use only and must be discarded after each use and which items are to be reprocessed after each use.
- b. Hands-on training for each endoscope and AER used at your facility, using the written instructions provided with each make and model. Work should be closely supervised until competency is documented for each reprocessing task from cleaning through storage of the endoscope.
- c. Additional training and documentation of competency whenever a new model of endoscope or AER is introduced into your facility
- d. Frequent reminders to all staff not to deviate from the written instructions for preparing endoscopes for patient contact.

2. Re-evaluate and document competency at periodic intervals.

II. Technical Aspects

A. Read and the follow the manufacturer's operating manual and instructions for use.

1. Clean, disinfect or sterilize, and assemble the endoscope according to the endoscope manufacturer's instructions.
2. Follow the endoscope manufacturer's instructions for high level disinfection or sterilization. If you do not use an AER, or in the absence of technical instructions for automated reprocessing of your endoscope, follow the manufacturers' recommendations for the detergent products and liquid chemical sterilant/ high level disinfectant products used at your facility. Be sure staff understands that enzymatic detergent solutions are single use and must be discarded after every use.
3. Check with your endoscope manufacturers to determine whether your endoscopes can be reprocessed in an AER and the steps that should be taken before reprocessing. Not all endoscopes can be reliably reprocessed in an AER. For example, the elevator-wire-channel of most duodenoscopes cannot be accessed by the AER. Such devices require manual reprocessing (manual cleaning and high level disinfection) for that channel, if not for the entire device. If not specifically indicated in the AER labeling, it is advisable to ask the AER manufacturer if the endoscope model you are using has been tested with their system.
4. Compare the reprocessing instructions provided by the endoscope and AER manufacturers and resolve any conflicting recommendations. Contact the manufacturers to resolve any conflicts, particularly when they involve the use of channel connections or capping/non-capping of specific lumens or channels.

B. Manually clean endoscopes before disinfection or sterilization

1. Make sure that all staff who handle soiled endoscopes understand the importance of manually cleaning the endoscope thoroughly before it is disinfected or sterilized, and that they have access to and comply with the endoscope manufacturer's instructions. It is imperative that staff flush all endoscopes immediately following each clinical procedure. Use of an enzymatic cleaner that is compatible with the endoscope is important in breaking down proteins that make up a large portion of common soil. In addition, staff should meticulously remove any debris or residuals collected in or on the endoscope, perform leak tests, and visually inspect the endoscope to ensure that it is in proper working order in accordance with the endoscope manufacturer's recommendations. **These steps are critical regardless of whether your facility manually reprocesses endoscopes or uses an AER.**
 2. Make sure that flexible fiberoptic endoscopes used as semi-critical devices undergo at least high level disinfection before each use. Semi-critical devices are those that contact intact mucous membranes such as the respiratory tract and the gastrointestinal tract. Most flexible fiberoptic endoscopes are semi-critical devices and require high level disinfection between patients.
 3. Make sure that endoscopes used as critical devices are sterilized before each use. Critical devices are those that contact sterile tissue or the vascular system. Endoscopes used in normally sterile body sites are critical devices and must be sterilized.
 - a. Low temperature sterilizers are available for reprocessing thermolabile flexible endoscopes. Some endoscopes, especially rigid ones, can be steam sterilized. Before sending an endoscope for sterilization, be sure to check the manufacturer's instructions for both the endoscope and the sterilizer to be sure that the devices are compatible and that the sterilizer is able to sterilize devices with the lumen length and diameter of the endoscope to be reprocessed.
 - b. Sterilization with a liquid chemical sterilant may not convey the same sterility assurance as sterilization achieved using thermal or low temperature chemical gas/plasma/vapor sterilization methods. Liquid chemical sterilants should be limited to reprocessing only critical devices that are heat-sensitive and incompatible with other sterilization methods. For more information see **Guidance for Industry and FDA Reviewers: Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants** (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/CDRH/CDRH%20Guidance%20for%20Premarket%20Notification%20Submissions%20for%20Liquid%20Chemical%20Sterilants/CDRH-G-07-001.pdf>) Also refer to the **CDC/HICPAC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008** (http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf).
 4. Incorporate a final drying step in your reprocessing protocol, as long as this is not listed as a precaution or contraindication in the manufacturer's instructions. This applies whether you manually reprocess your endoscope or use an AER. Studies have demonstrated that a final drying step that includes flushing all channels with alcohol, followed by purging the channels with air (to remove the alcohol), greatly reduces the possibility of recontamination of the endoscope by water-borne microorganisms. After reprocessing, store endoscopes in a manner that will minimize the likelihood of contamination or collection/retention of moisture.
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